

III. Remarks

A. Status of the Application

Claims 3, 10-17, 23-40, 43, 44, 56-61, 66, 67, 70, 71, 75, 76, 86-89, 91-96, 101-103, 106-110, 112-119, 121, and 122 are currently pending. Claims 56-61, 93-96, 101-103, 106-110, 112-119, 121, and 122 have been withdrawn from consideration as being directed to an unelected invention. Claims 75, 76, 86, and 87 are canceled by the present paper without prejudice to or disclaimer of the subject matter therein. No claims are added by the present paper. Applicants appreciate the indication of allowance for claims 91 and 92. Reconsideration of the present application in light of the following remarks is respectfully requested.

B. Rejections under 35 U.S.C. § 103

1. The Fuhrmann and Gauchet Patents

Claims 75, 76, 86, and 87 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,002,576 to Fuhrmann et al. ("Fuhrmann patent") in view of U.S. Patent No. 6,395,032 to Gauchet ("Gauchet patent"). Claims 75, 76, 86, and 87 are canceled by the present paper and, therefore, the rejection of these claims is moot and will not be addressed at this time.

2. The Buttner-Janz, Buechel, Fuhrmann, and Ray Patents

Claims 3, 10-17, 23-40, 43, 44, 66-67, 70, 71, 88, and 89 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,401,269 to Buttner-Janz et al. ("Buttner-Janz patent") in view of U.S. Patent No. 5,868,796 to Buechel et al. ("the Buechel patent"), in view of the Fuhrmann patent, in view of the Gauchet patent. Applicants respectfully traverse the rejection of these claims on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

a. Claims 3 and 10-15

With respect to independent claim 3 as presented by the present paper, the cited references fail to disclose, "a deformable, resilient central body disposed between and slidable with respect to the inner surfaces of the shells ... to allow the inner surfaces of the rigid opposing

shells and the outer surface of the central body to move easily with respect to each other within a constrained range of motion, but to resist such movement outside the constrained range of motion, wherein an upper portion and a lower portion of the outer surface of the central body are harder than an interior region of the central body disposed between the upper and lower portions; a flexible sheath extending between edges of the opposing shells, having an inner surface that, together with the inner surfaces of the rigid shells, defines a cavity containing the central body; and a liquid lubricant, which occupies at least a portion of the cavity between the central body and the opposing shells.” However, even when combined the Buttner-Janz, Buechel, Fuhrmann, and Ray patents fail to disclose such limitations. Specifically, the references fail to disclose or suggest having a liquid lubricant within a cavity and between a central body and opposing shells that are slidable with respect to one another as recited in claim 3.

In that regard, neither of the Buttner-Janz or Buechel patents appears to disclose a liquid lubricant as recited. Further, the opening 21 in the cover plate 3” of the Fuhrmann patent “serves to fill the interior with viscoelastic material—or, together with a similar opening, as ventilation.” Col. 4, Lines 10-12. In the Fuhrmann patent, the viscoelastic material fills a closed corrugated tube 1 to create the central spring body. Col. 2, Lines 52-67. The viscoelastic material 2 is the central body of the Fuhrmann device and is not a lubricant occupying “at least a portion of the cavity between the central body and opposing shells”. Accordingly, the opening 21 is clearly not for the “introduction of a lubricant into the implant between the central body and opposing shells,” as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form the central spring body. There is simply no disclosure or suggestion in the Fuhrmann patent of having a liquid lubricant between a central body and opposing shells that are slidable with respect to one another.

Similarly, the Gauchet patent also fails to disclose an implant having a liquid lubricant between a central body and opposing shells that are slidable with respect to one another. In that regard, the body 22 of the Gauchet patent is rigidly engaged with the lower plate 4 via “raised part 24 of the plate that extends into the body.” Accordingly, the body 22 is not slidable with respect to the lower plate 4. For at least these reasons, even when combined the Buttner-Janz,

Buechel, Fuhrmann, and Gauchet patents fail to teach all of the claimed elements of independent claim 3.

Further, there is no reason for combining the opening 21 of the Fuhrmann disc and fluid of the Gauchet patent with the devices of the Buttner-Janz and Buechel patents other than hindsight based on the present invention. In *KSR Int'l. Co. v. Teleflex Inc.*, the Supreme Court stated that

“A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” Id. at 14-15, emphasis added.

In the present case, the Examiner has not established any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the Buttner-Janz patent and the Buechel patent. The Final Office Action states that “it would have been obvious ... to modify the device of Buttner-Janz/Buechel/Bryan et al., as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant.” However, the devices of the Buttner-Janz patent include substantially solid core or central pieces. The central pieces of the Buttner-Janz patent are not formed by filling a tube with viscoelastic material as in the Fuhrmann patent. Accordingly, there is no reason, other than hindsight, why one skilled in the art would modify the devices of the Buttner-Janz patent include an opening for receiving viscoelastic material as disclosed by the Fuhrmann patent. Similarly, there is no indication why one would combine ventilation with the Buttner-Janz devices. Thus, there is no reason, other than hindsight based on the present invention, to combine the Fuhrmann patent and the Buttner-Janz patent in the manner suggested in the Office Action.

Similarly, the Examiner has not established any reason why a person of ordinary skill in art would combine the liquid filled chamber of the Gauchet patent with the devices of the Buttner-Janz patent. In that regard, the Office Action states that “it would have been obvious ... to modify the devices of Fuhrmann/Janz/Buechel et al; as taught by Ray et al., to create an increase volume in the nucleus cavity revitalizing the overall disc space.” Applicants presume the reference to the Ray patent is intended to be the Gauchet patent since the previously applied Ray patent is not included in the current Office Action. Regarding the proposed combination, the devices of the Buttner-Janz patent are themselves intervertebral disc endoprostheses that are to be inserted between two vertebrae. That is, the devices of the Buttner-Janz patent are already intended to revitalize the overall disc space. Unlike the Gauchet patent, the introduction of a fluid is not required to increase the size of the prosthesis to a sufficient size. In that regard, unlike the Fuhrmann and Gauchet patents, the devices of the Buttner-Janz patent are not inflatable or liquid-filled prostheses. Rather, the devices of the Buttner-Janz patent are “intervertebral disc endoprosthesis with two prosthesis plates ... and with a prosthesis core which cooperates with at least one prosthesis plate via an articular surface.” (Abstract). Further, there is simply no disclosure in the Gauchet patent (or the Fuhrmann patent) of filling devices as disclosed by the Buttner-Janz patent with a lubricant. Thus, there is no reason, other than hindsight based on the present invention, to combine the Gauchet patent and the Buttner-Janz patent in the manner suggested in the Office Action.

Finally, the Office Action entirely fails to address how the Buechel patent is being combined with the other references. Accordingly, Applicants are unable to determine what, if any, reason would motivate one skilled in the art to combine the Buechel patent with the Buttner-Janz, Fuhrmann, and Gauchet patents.

As noted above, the Supreme Court has established that “A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” Rather, it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” No such reasons have been identified in the current case.

Thus, a *prima facie* case of obviousness has not been established with respect to independent claim 3.

Claims 10-15 depend from and further limit independent claim 3. Therefore, for at least the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 10-15. Thus, Applicants request that the §103 rejection of claims 3 and 10-15 be withdrawn.

b. Claims 16 and 17

Independent claim 16 recites limitations similar to those discussed above with respect to independent claim 3. For example, claim 16 requires “a deformable, resilient central body disposed between the inner surfaces of the shells comprising an outer surface, at least a portion of which has a shape that compliments and articulates with the shape of the inner surfaces of the rigid opposing shells to allow the inner surfaces of the rigid opposing shells and the outer surface of the central body to slidably move easily with respect to each other within a constrained range of motion, but to resist such movement outside the constrained range of motion; and a lubricant positioned between the central body and the opposing shells; wherein the closable passage is configured in a manner that permits the introduction of the lubricant into the implant between the central body and the opposing shells.” As discussed above, the Buttner-Janz, Buechel, Fuhrmann, and Gauchet patents fail to disclose an implant having all of the recited limitations, including an implant having a lubricant between a central body and opposing shells that are slidable with respect to one another. Also, as discussed above, no “reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” has been identified.

For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 16. Claim 17 depends from and further limits claim 16. Therefore, Applicants respectfully request that the §103 rejection of claims 16 and 17 be withdrawn.

c. Claims 23-40

Independent claim 23 recites limitations similar to those discussed above with respect to independent claims 3 and 16. For example, claim 23 requires “an upper and a lower rigid,

opposed, biocompatible shell, each comprising: an outer, rough surface; an inner, smooth concave surface ... a deformable, resilient central body disposed between the inner, smooth concave surfaces of the upper and lower shells, comprising: a smooth convex upper surface adjacent to the inner smooth concave surface of the upper shell and a smooth convex lower surface adjacent to the inner smooth concave surface of the lower shell, the upper and lower surfaces being harder than an interior region of the central body disposed between the upper and lower surfaces ... and an elastic sheath disposed between the upper and lower shells and external to the central body ... and a lubricant disposed within the enclosed cavity surrounding the central body.” As discussed above, the Buttner-Janz, Buechel, Fuhrmann, and Gauchet patents fail to disclose an implant having all of the recited limitations, including an implant having a within a cavity surrounding a central body having smooth convex surfaces adjacent to smooth concave inner surfaces of upper and lower shells. Also, as discussed above, no “reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” has been identified.

For at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 23. Claims 24-40 depend from and further limit claim 23. Therefore, for at least the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 24-40. Thus, Applicants request that the §103 rejection of claims 23-40 over the Buttner-Janz, Buechel, Fuhrmann, and Gauchet patents be withdrawn.

d. Claims 43, 44, 66, 67, 70, and 71

With respect to independent claim 43 that was previously indicated as allowable, the Office Action entirely fails to address how the cited references could be interpreted to include all of the limitations recited therein. For example, claim 43 recites “an upper and a lower rigid, opposed biocompatible concavo-convex shell, each comprising ... a circumferential groove adapted to receive a retaining ring; a first ridge circumscribing the contact area of the inner concave surface and extending axially toward the opposing shell; a tab extending axially away from the opposing shell, and comprising an opening adapted to releasably engage a tool for

manipulating, inserting, or removing the endoprosthesis; a closable passage between the outer surface and the inner surface of the shell”, “a deformable, resilient central body disposed between the inner, smooth concave surfaces of the upper and lower shells, comprising: a shoulder circumscribing each of the smooth convex upper and lower surfaces and adapted to contact the first ridge of the adjacent shell and limit the relative motion of the shell with respect to the central body; a laterally extending equatorial ridge disposed between the first ridge of the upper concavo-convex shell and the first ridge of the lower concavo-convex shell”, “an upper retaining ring of a biocompatible material disposed in the circumferential groove in the upper concavo-convex shell and securing the upper edge of the elastic sheath to the shell and a lower retaining ring of a biocompatible material disposed in the circumferential groove of the lower concavo-convex shell and securing the lower edge of the sheath to the shell”, and “a plug of biocompatible material disposed in the closable passages between the outer surface and inner surface of at least one of the concavo-convex shells.” Claims 44, 66, 67, 70, and 71 depend from and further limit claim 43. Accordingly, Applicants submit that claims 43, 44, 66, 67, 70, and 71 are patentable over the cited references and request that the § 103 rejection of these claims be withdrawn.

e. Claims 88 and 89

With respect to independent claim 88, even when combined the Buttner-Janz, Buechel, Fuhrmann, and Gauchet patents fail to disclose an implant having all of the recited features of claim 88. In that regard, none of the cited references appear to disclose “wherein the opening is sealed with a plug tool having a handle and a detachable integral plug associated therewith after introduction of the lubricant into the cavity” as required. Further, the Office Action entirely fails to address these limitations of claim 88. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 88. Claim 89 depends from and further limits claim 88. In that regard, claim 89 further requires “wherein the plug detaches from the tool when a predetermined torque has been reached during insertion of the plug into the opening.” The cited references again do not appear to disclose such limitations and the Office Action entirely fails to address these limitations. Therefore, Applicants respectfully request that

the §103 rejection of claims 88 and 89 be withdrawn.

IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims under consideration are in condition for allowance.

The Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in this or any other Office Action associated with the present application.

A personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application.

Respectfully submitted,



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